# ALLERGY RELIEF CHILDRENS- diphenhydramine hcl tablet, chewable Amerisource Bergen

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### **Good Neighbor Pharmacy 44-599**

### Active ingredient (in each chewable tablet)

Diphenhydramine HCl 12.5 mg

#### **Purpose**

**Antihistamine** 

#### Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

#### Warnings

#### Do not use

- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

#### Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

#### Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

#### When using this product

- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages
- excitability may occur, especially in children

#### If pregnant or breast-feeding,

ask a health professional before use.

#### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- find right dose on chart below
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

Age (yr)	Dose (chewable tablets)
children under 2 years	do not use
	do not use unless directed by a doctor
children 6 to 11 years	1 to 2 chewable tablets (12.5 mg to 25 mg)
adults and children 12 years and over	2 to 4 chewable tablets (25 mg to 50 mg)

#### Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

#### Inactive ingredients

D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, ethylcellulose, flavor, hydroxypropyl cellulose, magnesium stearate, mannitol, stearic acid, sucralose, sucrose

#### Questions or comments?

1-800-426-9391

#### Principal display panel

# **Good Neighbor Pharmacy**®

Compare to Children's Benadryl® Chewables active ingredient\*

NDC 46122-425-89

For Ages 6-11

CHILDREN'S

# **Allergy Relief**

diphenhydramine HCl 12.5 mg / chewable tablets

Antihistamine

Relief of:

SneezingRunny Nose

Itchy Throat
Itchy, Watery Eyes

#### **Cherry Flavor**

Chew or crush tablets completely before swallowing. Do not swallow tablets whole.

**20** Chewable Tablets ι 12.5 mg Each

**Actual Size** 

Distributed By AmerisourceBergen 1 West First Avenue Conshohocken, PA19428 Questions or Concerns? www.mygnp.com

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Children's Benadryl<sup>®</sup> Chewables.

50844 REV1218B59909

#### **SATISFACTION GUARANTEED**

# TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

**GNP 44-599** 

# **ALLERGY RELIEF CHILDRENS**

diphenhydramine hcl tablet, chewable

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-425

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength	

**DIPHENHYDRAMINE HYDROCHLORIDE** (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) DIPHENHYDRAMINE HYDROCHLORIDE | 12.5 mg

#### **Inactive Ingredients**

Ingredient Name	Strength
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 30WL53L36A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

#### **Product Characteristics**

Color	pink	Score	no score
Shape	ROUND	Size	12mm
Flavor	CHERRY	Imprint Code	44;599
Contains			

### **Packaging**

# Item Code	Package Description	Marketing Start Date	Marketing End Date
<b>1</b> NDC:46122-425-89	4 in 1 CARTON	04/25/2011	
1	5 in 1 BLISTER PACK; Type 0: Not a Combination Product		

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/25/2011	

**Labeler -** Amerisource Bergen (007914906)

#### **Establishment**

Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(46122-425)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(46122-425)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		868734088	pack(46122-425)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(46122-425)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(46122-425)

Revised: 8/2021 Amerisource Bergen